Incontinence: the Engineering Challenge

The late 1970s were formative years for the incontinence world in general and for my involvement, in particular. Thomas et al. were surveying the patients of several UK GP practices in the first ever substantial study to determine the general prevalence of urinary and faecal incontinence, and discovering that both were far more common than had been realised [1]. Meanwhile, I was working to identify research priorities across a number of medical engineering sectors, and Thelma Thomas's data – generously shared with me pre-publication - provided a stark epidemiological opening to my report on incontinence technology. Other, equally stark, messages followed: existing products to contain incontinence were extraordinarily primitive, and I had failed to find a single current project in UK academic, industrial or clinical worlds that aimed to improve on them. The mismatch between need and current research effort was manifestly huge and – at the close of the project - I decided to focus my future work on incontinence technology.

Many other epidemiological studies have followed since Thomas et al.'s seminal work, confirming just how common incontinence is, and the most recent reviews suggest that around 10% of women in the western world suffer urine leakage at least weekly, and about half that number of men [2], while about 11% of adults (similar for both genders) suffer some degree of faecal incontinence [3]. Incontinence technology has improved in many ways in the forty years since the late 1970s but much remains to be done, and this special issue provides an excellent opportunity to take stock. Most of the papers address technology for <u>managing</u> incontinence. However, incontinence can often be cured - or, at least, reduced in severity - by attending to its underlying causes, and some of the papers address technology for <u>diagnosis</u> or <u>treatment</u>. Although all the papers relate to incontinence technology, few are written by engineers alone. Rather, authors include a pleasing mix of colleagues from the physical, life and social sciences together with clinicians, usually working in the multi-disciplinary contexts that increasingly characterise the groups active in the field, each member taking the time to become familiar enough with the language and culture of colleagues from other professions to enable fruitful synergies.

The Special Issue opens with a paper from Brian Buckley who encourages those of us seeking to develop improved incontinence technology to keep the needs and priorities of our intended end users central to our efforts. It's very easy for engineers to focus on the core functional requirements of a design – absorbing the urine; containing the faeces – and pay too little attention to less immediately obvious matters like ergonomics, comfort and discretion, that are just as important if a new product is to succeed. Brian outlines the factors that should be considered in drawing up a design specification, providing authoritative and accessible guidance that I would have loved to have had when I started out in the field.

The author of the next paper - Håkan Leander - has worked for many years on developing national and international standards relating to products for managing incontinence, latterly as chair of the pertinent International Standards Organisation sub-committee (ISO TC173 SC3). In his paper, he usefully reviews existing international standards and those currently under development, describing how such standards are developed and the uses to which they are put. As Håkan indicates, developing new standards can be time-consuming and challenging and the next paper focuses on one of the international standards currently under development, work that has so far taken more than 10 years. In it, my nursing colleague – Margaret Macaulay – and I report on work to evaluate the absorption before leakage (ABL) test that has been proposed as a new international standard laboratory method for measuring the absorption capacity of single use, body worn, absorbent products for heavy / moderate urinary incontinence. In our study, the test showed stronger correlation with user data than the existing international standard (the so-called Rothwell method), but it was more complicated, with poorer repeatability (within laboratories) and reproducibility (between laboratories). The ISO committee responsible for the development continues to work on refining the method.

In a second paper on absorbent products, Sabrina Falloon, Vasileios Asimakopoulos and I investigate the friction between product materials and skin that is thought to be a key causative factor for the incontinence-associated dermatitis (IAD) that users can often experience. We found that the ranking of coefficient of friction values across five commonly used fabrics was broadly similar for each subject, as it was also across the 19 subjects for each fabric, and we offer a model which successfully predicts the coefficients of friction for a given person-fabric in terms of the mean value across all fabrics for that person, and the mean value across all persons for that fabric. Interestingly, we found no systematic variation with subject age (20-95y) or with soft tissue compliance or skin smoothness. The work will hopefully help those keen to develop new fabrics that are kinder to the skin.

The following four papers focus on urinary catheters, the most common devices for managing urinary incontinence after absorbent products. Cathy Murphy – a research nurse – opens the sequence by reviewing and interpreting for an engineering readership the extensive clinical literature on catheters for both indwelling and intermittent use. This is enormously valuable and an excellent example of the important role that each member of a multi-disciplinary team has to play in making the insights and findings peculiar to their own discipline accessible to colleagues who might not otherwise be aware of them - still less able to understand and benefit from them, especially if they are presented in journals they don't read and within a culture and language foreign to them.

Cathy usefully explains who uses the various kinds of catheters and why, describes the functional requirements placed upon them, highlights their limitations and associated risks, suggests priorities for further work and makes a strong case for renewed efforts to move on from some design features – and associated problems - which have not changed greatly for some 80 years. In the following paper, Alberto Marzo and colleagues address indwelling catheters and their associated drainage systems from an engineering perspective. Drawing on the published literature and their own work they bring a range of analytical and experimental engineering methodologies to bear to suggest how catheter - and associated drainage tube - designs might be modified to reduce their potential for kinking and the incidence of the biofilm formation, encrustation and associated blocking that are commonly encountered.

In the third catheter paper, Scarlet Milo and colleagues focus on the last of these issues: indwelling catheter blockage caused by encrustation following catheter-associated urinary tract infection (CAUTI). They provide a helpful review of the efforts of the last ten years or so to address the core problem using engineering or medical strategies as well as stimuli-responsive approaches, in which a device responds actively to a triggering stimulus known to signal impending problems. It's particularly valuable that, as well as considering catheter-specific literature, their review also encompasses work in other contexts from which findings may be usefully transferred. But, despite the volume of work described, they report that few platforms have progressed to clinical studies, and even fewer to clinical practice. They conclude that stimuli-responsive approaches hold the most promise and underline the critical importance of a multi-disciplinary approach that draws on a broad spectrum of skills. The human and financial consequences of CAUTI are enormous, and the prospect of successfully addressing this challenge - surely the longest standing, unsolved problem in incontinence technology – is very exciting.

In the fourth catheter paper, Nicola Irwin and colleagues switch the spot-light to catheters for intermittent bladder drainage, focusing on the lubricious coatings that are commonly applied to the external surface of a catheter shaft to ease its insertion in the urethra. It is invariably quicker and simpler to measure the performance of incontinence devices in standardised laboratory tests than it is to gather data from user experience but, to be of most help, such laboratory methods need to be clinically validated; that is, shown to relate in a clear way to real use. In this paper, Nicola and colleagues report on work with a series of experimental catheters having a range of lubricious coatings in which they seek correlations between laboratory measurements of surface contact angles and coefficients of friction, and haptic assessment by a panel of volunteers, a half-way house to the trickier task of measurements in the urethra. Correlations were disappointingly poor in this initial work but several likely sources of noise in the haptic data were identified and focused method refinement is planned.

The academic and patent literature describe a plethora of attempts to use sensing technology to detect urinary incontinence events, either to inform caregivers and their practice, or to activate a pump that automatically draws urine away to a convenient location for later disposal. However, until quite recently, none has achieved successful commercialisation. Most progress has been made in Australasia and the USA, and in the next paper, Sangsoo Park and his colleagues from South Korea, explain the need for such devices and describe the design and performance of those currently available. It's interesting that significant inspiration for some of the newer devices involving a pump has come from designs developed for use by astronauts or by military aircraft pilots on long missions, useful spin-offs from settings in which the financial constraints on toileting arrangements are presumably rather less demanding than those commonly encountered in nursing homes. Sangsoo and colleagues suggest that sensing devices – with or without a pump - are set to become increasingly common as populations age, accompanied by an increasing demand for incontinence care and a decreasing availability of care staff.

Sensing of a different kind is at the heart of the next paper in which, by reviewing their own and others' work, Anisha Basu and colleagues assess the feasibility of bladder pressure monitoring using a submucosal sensor. If successful, such a device could be useful both diagnostically – by facilitating continuous ambulatory monitoring of bladder function – and for treatment, for example, alerting an individual with loss of sensation of the need to empty their bladder. The development of such a device is an ambitious undertaking but, in their recent animal work described here, Anisha and colleagues report good correlations between pressure measurements using their latest device and reference vesical pressures, and successful anchoring for reasonable periods of time. Further investigations into device miniaturization, anchoring methods, and understanding of submucosal pressure biomechanics are planned in support of progress towards clinical viability.

It's a truism of biomedical engineering that, before setting out to repair a malfunctioning physiological system, it's wise first to understand how it's supposed to work and in the next paper

Will Stokes and colleagues apply that principle to the human defecatory system. Their motivation is to create a platform for the development of improved technology for treating and managing faecal incontinence and related problems, and their strategy is to build a physical model with the potential both to illuminate normal and pathological function, and to provide a test bed for (prototype) devices. It's gratifying to read of their progress on both fronts: their model helpfully mirrors some important aspects of known physiological (mal)function and they report initial findings on using it to evaluate the FENIX magnetic sphincter implant, which aims to increase resistance to faecal leakage and reduce the anorectal angle required to maintain continence.

Fear of smelling is a very common source of anxiety among those with incontinence, and many restrict their interactions with other people in order to reduce the risk – real or imagined - of their smell giving away the secret of their incontinence. In this fascinating paper, Pamela Dalton and Christopher Maute, explain how the biological and psychological aspects of olfaction work, especially as they relate to the potentially stigmatising odours of urine and faeces. Over the years there have been many attempts to address the problem – mostly by aiming to eliminate, reduce or mask odours – and the paper provides a useful review of the literature, highlighting the strengths and limitations of each approach, underlining the importance of considering malodours in any work on incontinence technology, and providing valuable insights for anyone seeking strategies for tackling this aspect of their work.

The regulatory requirements to be met in bringing any product to market have grown enormously in recent years and nowhere more so than in the medical device sector. In his brief paper on the subject, Nick Donaldson argues that the point has now been reached where legislation intended to protect consumers can – in some cases – be to their disadvantage by denying them products that never reach the market because of the high financial burden of meeting regulatory requirements, particularly when they relate to small user groups such as paraplegic people in need of implants to restore their continence. Nick makes a compelling case for the deregulation of devices for such groups to avoid further disappointment and wasted research effort and money.

Pete Culmer and colleagues complete the collection with a white paper, focusing firmly on the future. Drawn from several of the UK Health Technology Cooperative and other networks with an interest in incontinence, they usefully combine perspectives from their diversity of disciplines to inspire and direct the research community towards unmet needs for technology to diagnose, treat or manage incontinence. They provide much detailed food for thought but also, usefully, reiterate several general points made in earlier papers, bringing them together in a coherent framework. They stress the need for user-centred design, and for designers to familiarise themselves with the broad context in which their technology will need to work, rather than limiting their attention to the core engineering challenges. We are reminded, again, of the great value of working in multi-disciplinary teams, the potential for importing technical innovations from other fields, and the significant challenges of regulatory and commercial considerations. They mention also the growing needs generated by the aging populations in many countries, but add another important dimension: co-morbidity. As we live longer, more and more of us will experience sustained periods with multiple long-term conditions that need managing together: how, for example, is incontinence best managed when it is combined with dementia or arthritis – conditions that may rule out solutions that would work well in their absence? Forty years ago, it was not unusual for companies to supply absorbent products described as "for incontinence", with the implied claim that they would suit users of either gender with urinary and / or faecal incontinence of any kind. Today's manufacturers, clinicians and users are more discerning and it is well recognised that two people with identically misbehaving bladders or bowels may prefer different ways of managing them, depending on their lifestyles, priorities and personal preferences: indeed, the same person may opt for different solutions in different contexts - home or away, sedentary or active, work or leisure, for example. The trend towards greater awareness of individual needs will surely continue, with comorbidities as the next important variable to come to the fore.

It's been interesting to be reminded of how incontinence technology has developed over the last forty years and encouraging to assemble a collection of papers that provide a snapshot of current activity, with the promise of better things to come. I may just live long enough to see a follow-up special issue in another forty years, but I may need some assistive technology to enable me to read it from my nursing home chair. I am also optimistic that the progress of technology in my chosen field will – by then – have advanced sufficiently to deliver trouble-free management of my bladder and bowel, if I can no longer manage them for myself!

References

[1] Thomas TM, Plymat KR, Blannin J, Meade TW. Prevalence of urinary incontinence. Br Med J. 1980 Nov 8; 281(6250): 1243-5.

[2] Milsom I, Altman D, Cartwright R, Lapitan MC, Nelson R, Sjöström, Tikkinen, KAO. Epidemiology of urinary incontinence (UI) and other lower urinary tract symptoms (LUTS), pelvic organ prolapse (POP) and anal (AI) incontinence, pp 22&35. In "Incontinence", 6th edition, 2017 (Ed Abrams P, Cardozo, L, Wagg, A, Wein, A.). International Continence Society, Bristol.

[3] Ng KS, Sivakumaran, Y, Nassar, N, Gladman, MA. Fecal incontinence: community prevalence and associated factors - a systematic review. Diseases of the Colon & Rectum, 2015; 58: 1194-1209.